IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**David Snyder**
Application No.	**:**	**10/537,792 From PCT/IB03/05812**
Filed	**:**	**June 6, 2005**
For	**:**	**EXTERNAL DEFIBRILLATOR WITH SHOCK ACTIVATED BY CESSATION OF PRECORDIAL COMPRESSIONS**

REPLY BRIEF

On Appeal from Group Art Unit 3762

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I. STATUS OF THIS APPEAL

A final rejection in this application was mailed December 10, 2008. A Notice of Appeal was filed on February 10, 2009. Applicant's Appeal Brief was filed on February 13, 2009, and an Appeal Brief correcting certain informalities in the original brief was filed on April 15, 2009. [Note: it appears from applicant's copy that the Appeal Brief suffered some sort of formatting problem and a duplicate copy of the April 15 Appeal Brief without the formatting problem is being submitted with this Reply Brief.] In response to the Appeal Brief applicant has received a further final rejection mailed July 21, 2009 which withdrew the finality of the December 10, 2008 Office action and stated new grounds of final rejection. This Reply Brief is submitted under 37 CFR §41.39(b)(2) to request that the appeal be maintained and to address the new grounds of rejection. No amendment to the claims or new evidence is being submitted with this Reply Brief.

II. STATUS OF CLAIMS

Claims 1-24 have been canceled and Claims 30-45 have been withdrawn. Claims 25-29 and Claims 46-57 are pending in the application. Claims 25-29 stand finally rejected and Claims 46-57 were

withdrawn by the Examiner in the Office action mailed December 10, 2008. The claims being appealed are Claims 25-29 and Claims 46-57.

III. NEW GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 46-57 were properly withdrawn from consideration as being directed to a non-elected invention;

B. Whether Claims 25-29 were correctly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of applicant's invention;

C. Whether Claims 25, 27-29 were correctly rejected under 35 U.S.C. §102(e) as being anticipated by US patent application publication no. 2004/0162585 (Elghazzawi et al.); and

D. Whether Claim 26 was correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Elghazzawi et al.

IV. ARGUMENT

A. Withdrawal of Claims 46-57 from consideration

This rejection is not a new rejection, as the same rejection was made in the December 10, 2008 Office action and was appealed and argued in applicant's Appeal Brief. Accordingly, applicant stands by the

position on this issue in the Appeal Brief and respectfully requests that the Board overturn the withdrawal by the Examiner of Claims 46-57 from this application for the reasons stated in the Appeal Brief.

B. Rejection of Claims 25-29 under 35 U.S.C. §112, second paragraph, as being indefinite for failure to particularly point out and distinctly claim the subject matter of applicant's invention.

In Claim 25, line 6, the phrase "the ECG signal" was said to have insufficient antecedent basis. It is respectfully submitted that this phrase does not render Claim 25 unclear or indefinite; the meaning of the claim remains clear. This is more a claim language informality. The suggestion here, to replace "the" with "a" is one which applicant will be pleased to do upon remand of this application following this appeal.

In Claim 25 the phrase "substantially no signal corruption" was said to be vague and indefinite. The term "signal corruption" is found throughout the specification in various forms including original Claim 1. The term "substantially" has its usual dictionary meaning: being largely but not wholly that which is specified. It is respectfully submitted that this phrase is not indefinite in the context of the present application.

In Claim 25 it was stated that steps (c) and (d) look to be part of step (b) and should be rewritten in that form. It is respectfully submitted that steps (b), (c), and (d) as presently constructed are clear and definite,

and the suggested rewriting is more a stylistic preference. Applicant will be pleased to rewrite this Claim as the Examiner suggests on remand of this application following the appeal.

C. Rejection of Claims 25, 27-29 under 35 U.S.C. §102(e) as being anticipated by US patent application publication no. 2004/0162585 (Elghazzawi et al.)

There are two responses to this ground of rejection. The first is that Elghazzawi et al. is of ineffective date to be a reference against these claims. The second is that, even if Elghazzawi et al. were a reference in this application, the reference fails to anticipate Claims 25-29.

The Elghazzawi et al. application has a filing date of February 19, 2003. There are no claims to any earlier priority. The present application claims the benefit of two US provisional applications, no. 60/433,375 filed on December 13, 2002 and no. 60/476,981 filed on June 9, 2003. The specification and drawings of this nonprovisional application serial no. 10/537,792 are identical to those of the December 13, 2002 provisional application, with two exceptions. In a previous Amendment in this case, a voice circuit/speaker 41 from the 2003 provisional application was added to the reference to a speaker on page 6, and the sensor 12 on page 10 which was said to include an accelerometer was moved to a later point in the paragraph. However neither the voice

circuit/speaker nor the accelerometer are mentioned in the pending claims. Accordingly it is respectfully submitted that Claims 25-29 are fully supported by and have the priority date of the December 13, 2002 application. Since this application is the national stage entry of an international application, its priority date is determined as explained by MPEP §1893/03(c), Part III. The chain of applications meets all of the requirements (35 U.S.C. §119(e), 37 CFR §1.78, copendency of applications, support for claims, designation of United States in the international application, all applications in English, claim of priority) for the December 13, 2002 priority of these claims. See also "Examination Guidelines for 35 U.S.C. §102(e), as amended by the American Inventors Protection Act of 1999..." at pages 7-8 issued by the Deputy Commissioner for Patent Examination Policy on December 11, 2002 and available on the USPTO Web page for the AIPA. Since the claims to which Elghazzawi et al. is applied have an earlier priority date than Elghazzawi et al., it is respectfully submitted that Elghazzawi et al. is ineffective as a reference against Claims 25-29, and to Claims 46-57 for the same reason.

When a victim is experiencing ventricular fibrillation, every moment of delay is significant as it brings the victim closer to disability or death. The invention of Claim 25 is designed to reduce the time to

resuscitation of the victim by defibrillation by looking for a premature termination of CPR compressions during a CPR period. CPR periods are generally programmed to be one to three minutes in duration, during which a rescuer is expected to apply precordial compressions to the chest of the victim at a prescribed rate of 100 compressions per minute. But rescuers unaccustomed to the rigors of CPR may tire and rest before the CPR period has come to an end. In that event a defibrillator carrying out the method of the present invention will identify the premature end of the CPR period by observing that there is substantially no signal corruption in the ECG signals and take that as an indication that precordial compressions are ended. The defibrillator will then analyze the ECG signal prior to the end of the original CPR interval to determine if a defibrillation shock is needed. If this analysis indicates that a shock is needed the defibrillator with then deliver the shock, which is conventionally done by flashing the shock button for the rescuer to press when he or she is clear of the victim. This inventive method enables a life-saving shock to be delivered if needed within seconds of a premature termination of CPR.

Elghazzawi et al. have two types of ECG analysis, termed "background analysis" and "foreground analysis." Foreground analysis is the careful, thorough analysis of an ECG signal that will reliably lead to a

shock delivery if needed. Background analysis is ECG analysis that is attempted during CPR. During CPR the background analysis looks for an interval of CPR which is sufficiently uncontaminated by chest compressions to classify the ECG rhythm. If the artifact-free ECG signal acquired is of insufficient duration to perform a reliable analysis, the background analysis resets and tries again. But if the analysis is sufficient to classify the ECG as a shockable rhythm, the defibrillator alerts the user to the presence of a shockable rhythm and switches to foreground analysis for a decision of whether to deliver a shock. See the final sentence of paragraphs [0025], [0027] and [0029]. Thus, the background analysis never results in a defibrillating shock. All it does is switch to the more detailed, more reliable foreground analysis, which determines whether a shock is to be delivered. Elghazzawi et al. explain the rationale for not using background analysis for shock delivery when they state "When the ECG analysis algorithm misinterprets CPR related ECG artifact as a shockable rhythm, it may advise the rescuer to prematurely stop performing CPR and to deliver a defibrillation treatment." See paragraph [0006]. Such an outcome is problematic in two regards: beneficial CPR is terminated prematurely, and a shock may be delivered to a patient who does not need one. Consequently Elghazzawi et al. prevent these problems by always using the more

reliable foreground ECG analysis to determine whether to deliver a shock.

The present invention avoids the wait for a second ECG analysis as Elghazzawi et al. do by making the shock determination from the analyzing step prior to the end of CPR and not waiting the additional time for a second ECG acquisition and analysis. Accordingly it is respectfully submitted that Claim 25 and its dependent Claims 26-29 cannot be anticipated by Elghazzawi et al.

D. Rejection of Claim 26 under 35 U.S.C. §103(a) as being unpatentable over Elghazzawi et al.

Claim 26 was rejected under 35 U.S.C. §103(a) as unpatentable over Elghazzawi et al. Claim 26 recites that the defibrillator is charged for delivery of a shock prior to the end of the CPR interval. This means that the defibrillator can be charged while the defibrillator is acquiring and analyzing an ECG signal interval and can be ready to deliver a shock if the analysis calls for one, further reducing the time to therapeutic shock delivery. Elghazzawi et al. do not state when their defibrillator is charged. One would presume it would be after a foreground analysis has determined that a shock is advised. Consequently it is respectfully submitted that Claim 26 is patentable over Elghazzawi et al.

There is a further reason why the present claims are patentable over

Elghazzawi et al., which is the different philosophy of their approach. Elghazzawi et al. are running their background analysis continually during CPR in the hope that they can grab a snippet of clean ECG signals between chest compressions which is sufficient for rhythm classification. They are trying to acquire a snippet which is just long enough ("at least X seconds") to perform an analysis. But Elghazzawi et al. are unwilling to issue a shock advisory based on this quick analysis, which is why they then switch to the foreground analysis state to determine whether to advise a shock. The present inventor has recognized the inadequacy of making a shock determination based on such inter-compression ECG snippets. Instead, the present inventor is looking for a cessation of CPR compressions. When a cessation of CPR is identified, artifact-free ECG signals of sufficient duration can be acquired to make a definitive determination of whether to advise a shock. This sharp difference in methodologies, looking for the cessation of CPR rather than an interval between compressions during CPR, is what makes the claimed invention clearly different and patentable over Elghazzawi et al. Accordingly it is respectfully submitted that Claims 25-29 and 46-57 are patentable over Elghazzawi et al.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 46-57 are not patentably distinct from Claims 25-29 and should not be withdrawn from this application. It is also respectfully submitted that Claims 25-29 are clear and definite, that Claims 25 and 27-29 are not anticipated by Elghazzawi et al. and that Claim 26 is patentable over Elghazzawi et al. It is further respectfully submitted that Claims 46-47 are patentable over the cited references. Accordingly, it is respectfully requested that this Honorable Board reverse the new grounds of rejection of these claims stated in the July 21, 2009 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 25-29 and Claims 46-57 are the claims involved in the appeal.

1. - 24. (canceled)

25. (rejected) A method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of:

(a) having the defibrillator initiate a cardio-pulmonary resuscitation (CPR) interval;

(b) prior to an end of the cardio-pulmonary resuscitation (CPR) interval, analyzing the ECG signal for signal corruption and, if a cessation or absence of CPR precordial compressions is indicated by substantially no signal corruption;

(c) analyzing an ECG signal prior to the end of the originally initiated cardio-pulmonary resuscitation (CPR) interval to determine if a defibrillation shock is needed; and,

(d) delivering a defibrillation shock if the analyzing step (c) indicates that a defibrillation shock is needed.

26. (rejected) The method of Claim 25, wherein step (c) includes charging the defibrillator prior to the end of the originally initiated cardio-pulmonary resuscitation (CPR) interval.

27. (rejected) The method of Claim 25, wherein step (c) includes determining whether a disturbance associated with the cardio-pulmonary resuscitation (CPR) interval is detected; and, if there is substantially no disturbance, delivering the defibrillation shock if needed.

28. (rejected) The method of Claim 25, further comprising the step of notifying an operator of the defibrillator prior to delivering the defibrillation shock.

29. (rejected) The method of Claim 25, wherein the defibrillation shock is provided about 10 seconds or less after the cessation of precordial compressions.

30. - 45. (withdrawn)

46. (withdrawn) A method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of:

prompting a start of a CPR therapy interval;

detecting an indication of CPR precordial compression cessation during the CPR therapy interval; and,

arming the AED for defibrillation shock delivery based on the detected cessation of precordial compressions detected during the CPR therapy interval.

47. (withdrawn) The method of Claim 46, wherein the arming step is complete in less than about 10 seconds from detection of the cessation of precordial compressions.

48. (withdrawn) The method of Claim 46, wherein the indication is based upon a predetermined end of the CPR therapy interval.

49. (withdrawn) The method of Claim 48, wherein the arming step includes initiating a charging of the high voltage energy source prior to the predetermined end of the CPR therapy interval.

50. (withdrawn) The method of Claim 48, wherein the arming step includes completing a charging of a high voltage energy source of

the defibrillator prior to the predetermined end of the CPR therapy interval.

51. (withdrawn) The method of Claim 48, further comprising the steps of:

obtaining an ECG signal from the ECG detector prior to the predetermined end of the CPR therapy interval; and

determining whether the ECG signal is corrupted by CPR activity, wherein the arming step is further based on determining an uncorrupted ECG signal.

52. (withdrawn) The method of Claim 46, wherein the indication of CPR cessation includes a signal generated by CPR activity.

53. (withdrawn) The electrotherapy method of Claim 52, further comprising the steps of:

obtaining an ECG signal from the ECG detector prior to the CPR cessation; and

determining whether the ECG signal is uncorrupted by CPR activity; wherein the arming step is further based on the determining step.

54. (withdrawn) A method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of:

coupling a plurality of sensors to the patient's body to detect physiological signals of the patient;

initiating a predetermined CPR therapy interval during which precordial compressions are to be administered to the patient;

monitoring a physiological signal received from at least one of the sensors to detect a cessation of precordial compression administration prior to the end of the predetermined CPR therapy interval;

upon detecting a cessation of precordial compression administration prior to the end of the predetermined therapy interval, obtaining ECG signals from a plurality of the sensors;

analyzing the obtained ECG signals to determine whether a defibrillation shock is needed; and

if the analyzing step determines that a defibrillation shock is needed, delivering a defibrillation shock to the patient through a plurality of the sensors.

55. (withdrawn) The method of Claim 54, wherein one of the sensors detects a signal indicative of patient movement due to CPR motion,

wherein the signal indicative of patient movement is used in the detecting step.

56. (withdrawn) The method of Claim 54, wherein one of the sensors detects a signal indicative of ECG signal corruption from CPR activity,

wherein the signal indicative of ECG signal corruption is used in the detecting step.

57. (withdrawn) The method of Claim 54, further comprising the step of initiating charging of a high voltage energy source prior to the predetermined end of the predetermined CPR therapy interval.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.